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10/726,110	12/02/2003	Gary Searle	03-062-GS	4782

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LAMBERT & ASSOCIATES  
SUITE 200  
92 STATE STREET  
BOSTON, MA 02109

EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/726,110

Applicant(s)

SEARLE, GARY

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 2,8,15,24-75 and 78-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-14,16-23,76 and 77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1-26-04
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 2,8,15,24-75,78-105 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/27/04. Applicant stated that claims 15, 78-81, 84, and 100-105 read on the elected species. Examiner found that these claims do not apply to the elected species.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 includes the trademark "Elgiloy." Claim 3 should also have the word "body" inserted after the word "stent" for clarification of the part that is formed of the shape memory metal.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 76 and 77 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,517,575 to Yang.

Yang discloses a self-expanding stent that is in the form of a rolled sheet. The rolled sheet has many layers, including a layer of expandable filler material. Yang explains that the expandable filler material swells upon absorbing water when placed in a body lumen (column 2, lines 45-50 and column 4, lines 60-65).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1,4,5,9-14, 16,19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,458,152 to Khosravi et al. in view of Yang.

Khosravi discloses a rolled sheet self-expanding stent that includes layers of different materials. One layer, or "stent body" is formed from a shape memory metal (column 6, lines 40-45). A polymeric layer is disposed on the interior of the stent body and can be in the form of several layers (column 3, lines 35-45). An additional polymer layer can be disposed on the exterior of the stent to form a "barrier film", and it can be porous (column 5, lines 35-50). An alternate barrier film encapsulating the stent is disclosed (column 7, line 61 through column 8, line 5). The stent can also include a coating of heparin (column 8, lines 63-65). A balloon catheter can be used for implantation (column 9, line 36 and Figure 5B).

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Khosravi fails to include an expandable filler material, but does state that the inner polymer layer can be formed as several layers (column 3, lines 35-45). Khosravi also requires a balloon catheter for aiding in the expansion of the prosthesis. As explained above, Yang also discloses a rolled sheet self-expanding vascular prosthesis. Yang teaches that this type of prosthesis should include an expandable filler material bonded to another thin sheet. The expandable material aids in the self-expansion of the stent, as it causes the sheet to unroll and expand as the material swells when in contact with water in the body lumen. Yang also explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3). These statements provide motivation to combine the Yang and Khosravi devices. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the multilayered polymer portion of the Khosravi stent as an expandable filler material bonded to a thin sheet, as Yang teaches that this combination of materials aids in the self-expansion of a rolled sheet stent. The expanding material may be capable of replacing the use of a balloon catheter.

Yang states that the expandable layer may be biodegradable and gives many examples of materials that can form the expandable polymer layer in column 3. The expandable layer (20) is disposed on a thin sheet of material that can be polymeric or metallic (10) (column 2, lines 55-60). Yang explains that other types of layers, including metal, may be formed with the rolled sheet stent (column 2, line 65 through column 3, line 3).

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Claims 10 and 13 only include limitations pertaining to the method by which the product is made. Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. Therefore, the limitations of claims 10 and 13 were not given patentable weight.

Claims 19-21 only pertain to intended use of the device. The only requirement here is that the prior art stent be capable of performing these functions. Since the Yang stent is capable of being used with another stent and in procedures pertaining to animals or humans, it meets the limitations of claims 19-21.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of US Patent No. 6,042,605 to Martin et al.

The modified Khosravi device fails to form the stent body from a cobalt-chrome alloy, or Elgiloy. Khosravi does state that the stent body can be formed of nitinol or stainless steel (column 6, lines 41-45). Martin discloses a stent body disposed over a polymer graft. Martin teaches that Elgiloy is a suitable material to use as a substitute for nitinol, as it is highly resilient (column 11, lines 5-40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Elgiloy for nitinol for the material of the stent body of the modified Khosravi stent, as Martin teaches that Elgiloy has good mechanical properties for forming stents.

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6. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of US Patent No. 6,428,571 to Lentz et al.

As explained above, Yang discloses many different materials for forming the expandable layer in column 7. Among those materials are gelatin, collagen, albumin, and starch. Lentz teaches that casein is another natural material equivalent to gelatin, collagen, albumin, and starch for forming expandable polymer layers (column 8, lines 38-49). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include casein in the expandable filler material of the modified Khosravi device, as Lentz teaches that casein is simply an alternate natural material for forming expandable polymer layers.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi in view of Yang, as applied to claim 1 above, and further in view of US Patent No. 5,824,046 to Smith et al.

Khosravi states that the outer polymer layer, or "barrier film", can be formed of graft materials, such as PTFE, polyester, or urethane (column 7, lines 11 and 64). Smith discloses a stent with a polymeric outer layer. Smith teaches that polypropylene is a suitable substitute for PTFE, polyurethane, and polyester for forming the barrier film (column 7, lines 32-56). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the barrier film of the modified Khosravi device of polypropylene, as Smith teaches that this material is suitable for forming a barrier film for a stent.

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### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW

11/09/04



DAVID O. REIP  
PRIMARY EXAMINER